

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 121

Organ Procurement and Transplantation Network

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final Rule

SUMMARY: This document sets forth improvements to the final rule governing the operation of the Organ Procurement and Transplantation Network (OPTN), published in 1998. It reflects the advice of a panel convened by the National Academy of Science's Institute of Medicine, as called for in the Department's appropriation act for 1999. It also reflects comments on the 1998 rule and consultation with representatives of the organ transplantation community, as recommended in the same legislation; and it summarizes new transplant data developed in the period since enactment of the appropriations act.

DATES: The final rule published on April 2, 1998, 63 FR 16296, adding 42 CFR part 121 with an effective date of October 1, 1998, as amended on July 1, 1998, 63 FR 35847, did not take effect under section 213(a) within Public Law 105-277, 112 Stat. 2681, 2681-359 through 2681-360, approved October 21, 1998. The April 2, 1998 rule as amended by this document, is effective on November 19, 1999.

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SUPPLEMENTARY INFORMATION: On April 2, 1998, the Department of Health and Human Services (HHS) published in the Federal Register a final rule pertaining to the operation of the Organ Procurement and Transplantation Network (63 FR 16296). In accordance with the National Organ Transplant Act (NOTA) of 1984, as amended, the purpose of the final rule is to help achieve the most equitable and medically effective use of human organs that are donated in trust for transplantation. Toward this end, the final rule establishes performance goals intended to bring about: 1) standardized criteria for placing patients on transplant waiting lists, 2) standardized criteria for defining a patient's medical status, and 3) allocation policies that make most effective use of organs, especially by making them available whenever feasible to the most medically urgent patients who are appropriate candidates for transplantation. The final rule also sets standards for availability of organ transplantation data, and it addresses the governing structure of the OPTN. No provision of the final rule is intended to interfere with the discretion of individual health professionals and patients in

medical decision-making, and the rule looks to the OPTN to design organ allocation policies. At the same time, the rule defines the policy oversight responsibilities of the Secretary of HHS. In concert with efforts to encourage organ donation, the final rule is intended to help make best use of the limited number of organs available for transplantation.

The final rule invited further comments, which have been received and reviewed. In addition, the Omnibus Consolidated and Emergency Supplemental Appropriations Act for 1999 delayed implementation of the final rule until October 21, 1999. (This Omnibus Act, Public Law 105-277, at section 101(f) of Division A, enacted the Department of Labor, HHS, and Education, and Related Agencies Appropriations Act, 1999. Within the latter act, section 213 included provisions related to the final OPTN rule, 112 Stat. 2681, 2681-359 through 2681-360. Hereafter, for ease of reference, we will refer to section 213 of the Appropriation Act, or simply section 213.) Section 213 called for independent review through the National Academy of Science's Institute of Medicine. It also suggested development of improved information on the effectiveness of the transplantation system, including center-specific information if possible. Finally, it suggested further discussions between HHS and representatives of the transplant community. Each of these areas has been addressed.

I. Background

A. Legislative and Regulatory History

Legislative and regulatory history are outlined in the preamble to the April 2, 1998, final rule. In addition to the underlying statute (sections 371-376 of the Public Health Service Act, as enacted by the National Organ Transplant Act of 1984, and as subsequently amended), of particular importance is section 1138 of the Social Security Act, enacted in 1986. This legislation requires hospitals that perform organ transplants to be members of, and abide by the rules and requirements of, the OPTN as a condition for participation in the Medicare and Medicaid programs. This provision subjects a transplant hospital's entire Medicare and Medicaid participation, and thus in reality its economic survival, to OPTN policy and enforcement. A similar provision in section 1138 affects funding under Medicare and Medicaid for organ procurement organizations (OPOs). But authority for establishing conditions of participation in Medicare and Medicaid resides with the Secretary and cannot be exercised by another party without either oversight authority or delegation. Thus, review and

oversight authority of OPTN policies by the Secretary of HHS is made even more necessary by section 1138. A Federal Register notice published on December 18, 1989 (54 FR 51802) addressed this need by stating that no OPTN policies are legally binding “rules or requirements” of the OPTN for purposes of section 1138, unless they have been approved by the Secretary. The final rule published April 2, 1998, defines the structure for such review and approval, thus setting the stage for OPTN “rules or requirements” that would be enforceable on transplant hospitals and OPOs under section 1138.

In October 1998, section 213 of the Appropriation Act delayed implementation of the final rule to October 21, 1999. Section 213 directed that the Institute of Medicine conduct a review of the current policies of the OPTN and the final rule. Section 213 also suggested that the Secretary “may conduct a series of discussions with the OPTN in order to resolve issues raised by the final rule.” In addition, section 213 indicated a need for improved availability of data on transplantation and transplant center performance.

B. Institute of Medicine Report

The Institute of Medicine (IOM) issued its report, *Organ Procurement and Transplantation*, on July 22, 1999. The report included five major recommendations. The Department has relied heavily on the guidance in the IOM report in reviewing the provisions of its final rule. In general, the IOM report validates the concerns that gave rise to the final rule and the approaches taken in the rule:

RECOMMENDATION 1: *Establish Organ Allocation Areas for Livers.* The committee recommends that the DHHS Final Rule be implemented by the establishment of Organ Allocation Areas (OAAs) for livers - each serving a population base of at least 9 million people (unless such an area would exceed the limits of acceptable cold ischemic time). OAAs should generally be established through sharing arrangements among organ procurement organizations to avoid disrupting effective current procurement activities.

RECOMMENDATION 2: *Discontinue Use of Waiting time as an Allocation Criterion for [Liver Transplant] Patients in Statuses 2B and 3.* The heterogeneity and wide range of severity of illness in statuses 2B and 3 make waiting time relatively misleading within these categories. For this reason, waiting time should be discontinued as an allocation criterion for status 2B and 3 patients.

An appropriate medical triage system should be developed to ensure equitable allocation of organs to patients in these categories. Such a system may, for example, be based on a point system arising out of medical characteristics and disease prognoses rather than waiting times.

RECOMMENDATION 3: *Exercise Federal Oversight.* The Department of Health and Human Services should exercise the legitimate oversight responsibilities assigned to it by the National Organ Transplant Act, and articulated in the final rule, to manage the system of organ procurement and transplantation in the public interest. This oversight should include greater use of patient-centered, outcome-oriented performance measures for OPOs, transplant centers, and the OPTN.

RECOMMENDATION 4: *Establish Independent Scientific Review.* The Department of Health and Human Services should establish an external, independent, multidisciplinary scientific review board responsible for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible.

RECOMMENDATION 5: *Improve Data Collection and Dissemination.* Within the bounds of donor and recipient confidentiality and sound medical judgment, the OPTN contractor should improve its collection of standardized and useful data regarding the system of organ procurement and transplantation and make it widely available to independent investigators and scientific reviewers in a timely manner. The Department of Health and Human Services should provide an independent, objective assessment of the quality and effectiveness of the data that are collected and how they are analyzed and disseminated by the OPTN.

In addition, the General Accounting Office (GAO) made findings in two other areas required by section 213: the possibility of legal liability of OPTN members arising from their peer review activities and the confidentiality of information. Regarding liability, the General Counsel of the GAO found no apparent conflict between the final rule and State laws governing peer review. Regarding confidentiality, the General Counsel found that the Secretary of HHS has authority under the final rule to decide that the

public interest in disclosure of information about organ transplants outweighs the interest in confidentiality.

C. Discussions with the Transplant Community

Representatives of HHS met with members of the transplant community on numerous occasions in the period immediately following publication of the final rule. Since enactment of section 213, representatives of HHS have met on 11 separate occasions with representatives of 11 transplant organizations: United Network for Organ Sharing (UNOS, the current OPTN contractor), Transplant Recipients International Organization, American Liver Foundation, National Transplant Action Committee, National Minority Organ and Tissue Transplant Education Program, National Kidney Foundation, Patient Access to Transplantation Coalition, American Society of Transplantation, American Society of Transplant Surgeons, North American Transplant Coordinators Organization, and the American Nephrology Nurses Association. On September 15, 1999, an additional meeting with representation invited from all of these organizations took place to discuss together issues that had been surfaced.

Clarifications -- HHS is further clarifying these issues with this publication:

c “National” lists: The final rule does not require single national lists for allocation of organs, beyond the national registry lists already utilized by the OPTN. As underscored by the IOM recommendations, it is the Department’s goal to achieve sharing of organs broad enough to achieve medically effective results for patients, especially by providing organs for patients with greatest medical urgency who are appropriate candidates for transplantation. When using the terms “greatest medical urgency,” or “most medically urgent,” the Department is referring to transplanting those patients whose medical condition, in the judgment of their physicians, makes them suitable candidates for transplantation. The final rule directs the OPTN to overcome as much as possible arbitrary geographic barriers to allocation that restrict the allocation of organs to patients with greatest medical urgency who are appropriate candidates for transplantation and that are not based on medical criteria. Broader sharing was an essential element of the IOM’s findings.

c Most Medically Urgent Patients: The final rule follows, and intends to expand, existing policy in serving most medically urgent patients first, again, referring to patients who are suitable candidates for transplantation. It is not the Department’s intention to

require transplantation of patients too ill to benefit; the final rule specifically prohibits policies that might result in such futile transplantations and organ wastage. Providing available organs to patients with greatest medical urgency who are appropriate candidates for transplantation is already the policy of the OPTN within allocation areas. Transplant priority for patients with greatest medical urgency, whenever they are medically suitable, follows the tenets of medical practice generally and is already accepted throughout the transplant community and general public.

c Medical Factors Affecting Organ Movement: The final rule fully recognizes limitations on movement of organs resulting from medical factors, especially limits of ischemic time. As recommended by the IOM report, and as intended by the 1998 final rule, sharing of organs should be broad enough to enable medically effective use of organs, especially to enable organs to reach the most medically urgent patients, but ischemic time limits and any other medical factors affecting the viability of the organ must be considered in designing allocation policies.

c Small and Medium Sized Transplant Centers: The Department does not expect the final rule to cause the closure of small or medium sized transplant centers or otherwise diminish access to transplantation for certain populations, including those living in rural areas. The IOM report did not find evidence that the rule would have such effects; and a report by the HHS Office of Inspector General (“Fostering Equity in Patient Access to Transplantation: Local Access to Liver Transplantation,” dated August 1999) concluded that geographic distribution of liver transplant centers is unlikely to change as a result of national policies on organ allocation. The Department is concerned that patient access to transplant services not be adversely affected by closure of centers that are providing quality care, including small and medium sized centers. Thus, the amendments below include provision for monitoring any effects of policy changes on small and medium sized centers. However, HHS and the OPTN should work together to ensure that all transplant programs, regardless of volume, are providing quality care to candidates and recipients.

c Designated Transplant Program Requirements: The final rule carries forward the policies in the proposed rule that provided separate staffing and organizational “designated transplant program” requirements for non-Medicare participating transplant programs and those that are certified as Medicare approved transplant

programs. The Department has received comments similar to those submitted in response to the proposed rule, suggesting that uniform standards be applied for designation status. The Department continues to have no objection to this suggestion in principle, but believes that the OPTN should submit such standards for the Secretary's consideration as possible changes to the Medicare conditions for coverage of organ transplants, which currently contain similar requirements.

Secretarial Oversight and Enforceability of OPTN Policies -- Virtually all commenters agreed that HHS should exercise an oversight role over OPTN policies, although there were different views among the participants as to how such oversight should be carried out. Exercise of HHS oversight was also one of the five primary recommendations of the IOM report. Further, as explained in "Legislative and Regulatory History" above, section 1138 of the Social Security Act elevates OPTN membership and policies to the status of requirements for participation in Medicare and Medicaid for transplant hospitals and OPOs, thus necessitating Secretarial review and oversight authority over those policies. The final rule provides the framework for such oversight as well as the framework for creating a body of enforceable OPTN policies.

An additional recommendation by the IOM was establishment of an independent scientific review board "for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible." In response to this recommendation in the IOM report as well as comments received, the Department intends to create such an advisory board, the Advisory Committee on Organ Transplantation. The Department intends to implement the IOM's recommendations that this Committee have several key responsibilities. As recommended by the IOM, the Committee will provide "timely, nonpartisan review" to "assist the Secretary in managing the system in a manner that best serves the public interest." It will also, as recommended by the IOM, "help provide objective information and advice for future directions for the [organ transplantation] system." It would also, as recommended by the IOM, "help insure that policies and procedures are evidence-based and guided by the best available scientific and medical precepts." In order that the Committee fulfill this latter responsibility, § 121.4(b)(2) and (d) have been revised to reflect this role.

When the OPTN proposes enforceable policies, the Secretary will ask the Committee for its views on the proposals when the proposals are published in the Federal

Register for public comment. The Committee's views, public comments, and the Department's views will then serve as the basis for discussions with the OPTN. If, after these discussions, the Secretary wishes to direct that the OPTN revise its proposals, the OPTN will have the opportunity to suggest revisions. If the Secretary does not agree with the OPTN's revised approach (or if it does not respond in a timely manner), the Secretary may require the OPTN to take other appropriate actions. However, the Secretary will ask the Committee for its views on the specific proposed actions before transmitting them to the OPTN. A similar approach may also be used should the Secretary review other OPTN policies, or elect to evaluate critical comments received by the Secretary relating to the manner in which the OPTN is carrying out its duties.

It is not the desire, nor is it the intention, of the Department to interfere in the practice of medicine. Decisions about who should receive a particular organ in a particular situation involve levels of detail, subtlety, and urgency that must be judged by transplant professionals. The Advisory Committee will greatly assist the Secretary with respect to the medical and scientific components of OPTN policies. The medical community has substantial contributions to make within the deliberative process for developing OPTN policies, as well as in individual decisions involved in clinical transplantation practice.

The rule also has been revised to emphasize that the Secretary's review is intended to ensure consistency between OPTN policies and the National Organ Transplant Act and this regulation. This revision is intended to emphasize, as the IOM did in its report, that the Secretary's oversight will further the public interest, a role assigned to the Department by the National Organ Transplant Act and articulated in this regulation.

OPTN Board Composition -- Participants expressed a variety of views on requirements concerning the composition of the OPTN Board of Directors. Some participants believed that the rule should require, not merely authorize, the Board to include at least 50 percent representation of transplant physicians and transplant surgeons, to ensure a preponderance of medical expertise. Others suggested more even division of representation among transplant physicians and transplant surgeons, other non-physician transplant professionals, and candidates, recipients, donors, their families, and the general public. Concern was also raised that a combination of percentage representation requirements with specific categorical representation requirements would make the Board so large as to be unwieldy, if the Board chose to allow 50 percent representation of transplant physicians and surgeons. The

Department has reorganized and revised the Board and Executive Committee composition provisions to strengthen the role of transplant physicians and surgeons on the Board, consistent with the rule's thrust that allocation policy (one of the OPTN's most important responsibilities) be based on objective and measurable medical criteria and sound medical judgment, to strengthen the role of transplant candidates, recipients, donors, and their families on the Board and its Executive Committee, and to provide the OPTN greater flexibility in determining the appropriate size for the Board. This document includes amendments that identify categories of membership, but do not require a specific number of members from each category. This amendment requires approximately 50 percent transplant physician or transplant surgeon membership, instead of no more than 50 percent, and specifies at least 25 percent transplant candidates, transplant recipients, organ donors, and family members.

We have retained the provision designed to avoid even an appearance of a conflict of interest by requiring that transplant candidates, recipients, donors and family members on the Board not have an "employment or similar relationship" with certain entities and individuals involved in transplantation. However, we received comments suggesting that such individuals may have exceptional commitment or knowledge and should not be automatically disqualified from Board membership, and that, in any event, the Board should have additional flexibility in this area. We have revised this provision to authorize the Board to waive this requirement for up to half of these members. We expect the Board to use this flexibility consistent with the rule's goal of broad involvement of patients, recipients, donors, families and the public in the formulation of transplant policy.

Broader Geographic Sharing of Organs -- The final rule's emphasis on broader sharing of organs is being clarified through this document. Establishment of liver allocation areas broad enough to provide for medically effective allocation of organs was the leading recommendation of the IOM report. Some commenters expressed concern about the need for the transplant system to use standard criteria for listing patients and assigning their urgency status, and likewise the need for enforcement mechanisms to ensure that medically urgent patients who are appropriate candidates for transplantation are not disadvantaged through misuse of listing criteria or priority rankings. The final rule calls on the OPTN to develop such standard criteria, and to monitor compliance with them, prospectively if appropriate. Further, by establishing a framework for Secretarial review and approval of OPTN policies, as well as review and evaluation procedures for the

OPTN, the rule provides a foundation for enforcement of these standard criteria.

Frequency and Timeliness of Data -- Most participants expressed support for enhanced frequency and timeliness of data. Likewise, the IOM report strongly urged improvements in data collection and dissemination, both for physician and patient information and to provide outcome data that may improve understanding of best medical practices. As OPTN contractor, UNOS expressed concern about its ability to meet the frequency requirements in the April 2 final rule. The Department has decided to retain the 6 month data presentation requirement. The Department recognizes that UNOS' concerns stem in part from its belief that certain types of data may not need to be updated as frequently as others. Therefore, the Department has added a provision that would permit longer intervals for certain data.

The Department recognizes the progress that UNOS has made in increasing the availability of program-specific information for use by patients, families, physicians, and payors. To respond to the contractor's concerns regarding its ability to meet the frequency of the reporting requirement in the final rule, HHS will not require the submission of the first program-specific report under §121.11(b)(1)(iv) until June 30, 2000. This will allow OPTN member organizations adequate time to become fully Y2K compliant and ensure that all data submitted to the OPTN is done so electronically, and will enable the contractor to meet the Department's and the IOM's expectations that information be more timely and accessible.

Use of Waiting Time -- In general, the IOM found the emphasis on cumulative waiting times to be inappropriate as a measure of equity in the transplant system and as a criterion for allocation for less medically urgent patients, pointing instead toward "more meaningful indicators of equitable access" such as "status-specific rates of pretransplantation mortality and transplantation." The IOM report indicated, however, that the use of "waiting times in status" for the most medically urgent liver transplant patients (those in status 1 and 2A) was "an appropriate criterion, along with necessary medical criteria." For less medically urgent patients (statuses 2B and 3), the IOM recommended that the OPTN discontinue use of waiting time as an allocation criterion and instead develop "an appropriate medical triage system . . . to ensure equitable allocation of organs to patients in these categories." HHS generally agrees with these findings, although the Department believes that waiting time in status (unlike cumulative waiting time) can be one among several useful criteria in assessing variability in results for patients at

different transplant centers. To date, waiting times have been used in examining the performance of the transplant system in part because waiting times are used by the OPTN as an allocation criterion, and in part due to lack of better measures. It is for these reasons that reducing any variations in “waiting time in status,” especially for the most medically urgent patients, was included as a performance measure in the final rule published April 2. In addition, the IOM recommendation points again to the need for better data to provide alternatives to waiting time as a performance measure. Based on the IOM’s recommendations and comments from the transplant community, the Department has made additional refinements to the rule’s discussion of waiting times.

The Department’s approach in this section follows the recommendations of the IOM and responds to issues raised by commenters. First, the Department agrees with the IOM recommendations that “overall” waiting times are an inappropriate measure. The concept of using “waiting time in status” is, however, permitted as a factor in allocation policy.

Second, §121.8(b)(4) requires the OPTN to use performance indicators to assess transplant program performance and to seek to reduce the variations among transplant programs with respect to selected performance indicators. This “performance indicator” approach is consistent with the IOM’s recommendation that data be used to assess transplant program performance. Among the alternatives available to the OPTN is the performance indicator “waiting time in status.” Consistent with the IOM’s approach, if the OPTN retains waiting time in status for allocation purposes for medically urgent categories similar to current Status 1 and 2A in its revised liver allocation policies, the Department would expect the OPTN to use waiting time in status as a performance indicator for liver patients, along with necessary medical criteria.

Regarding the general approach of reducing variations among transplant programs with respect to selected performance indicators, we also expect the OPTN to work towards improving, where possible, the outcomes under these indicators. For example, if the OPTN used the performance indicator pretransplantation mortality rates for liver patients by medical status, as recommended by the IOM, then the Department would expect the OPTN to seek to reduce the variations in this performance indicator by improving pre-transplant survival at programs where it fell significantly below the national rates.

We also note that, although §121.8(b)(2) requires that the medical characteristics of patients within each category

be as similar as possible, the IOM observed that the current liver status categories 2B and 3 were heterogeneous. As a result, some patients in these categories need life-saving transplants sooner than others. The other patients, often with longer waiting times, can, nevertheless, wait longer periods of time without increased risk of death. Therefore, the IOM concluded that the OPTN should not use waiting times as a criterion for patients in these categories. Some commenters, however, suggested that the OPTN would have difficulty further refining its existing status categories. Commenters also requested that the OPTN be allowed to continue to use waiting times in some fashion for these patients. This rule provides the OPTN flexibility to continue to use waiting times for patients in these categories but would require that such use not override medical urgency considerations.

However, the Department expects, as the IOM concluded, that broader sharing of organs should occur for all patients and that organs will go to more medically urgent patients who are appropriate candidates for transplants before being offered to patients whose condition permits them to wait longer for a transplant.

OPTN Review of Member Compliance with Final Rule Requirements and Mandatory OPTN Policies -- Many members of the transplant community expressed concern about how best to promote compliance with OPTN policies. Section 121.8(a)(7) has been added to emphasize that the OPTN should especially promote compliance with approved allocation policies through prospective and retrospective reviews of programs’ compliance with allocation policies. In addition, the OPTN is required by §121.10 to conduct reviews and evaluations of each OPTN member’s compliance with these rules and approved OPTN policies. Thus, the OPTN is required to implement a review process to ensure that individuals receiving transplants are accurately listed and in proper classification categories to receive organs. Currently, UNOS liver and thoracic Regional Review Boards (RRBs) provide retrospective review of designation of status 1 and 2A patients for livers and 1A patients for hearts. The Department will explore with the OPTN contractor issues related to the conduct of prospective and/or retrospective reviews of all listings and changes in status categories to assure that programs are making appropriate classification determinations. Reviews, prospective and retrospective, might be performed by existing OPTN RRBs. In addition, the Secretary may ask independent third parties, such as the Joint Commission on the Accreditation of Health Organizations (JCAHO), or Utilization and Quality Control Peer Review Organizations (PROs) established under Part B of title XI of the Social

Security Act, to monitor the OPTN enforcement system by independently conducting audits of the work of the RRBs.

Incentives for High Performing OPOs -- Concern has been expressed that, by emphasizing broader sharing of organs, the final rule might bring about reduced organ donation. The Department disagrees, and the IOM report found some evidence that, where broader sharing is currently occurring, donations have increased. In response to these concerns, however, HHS has considered the possibility that positive rewards might be offered for high performing OPOs, to add to incentives for organ donation. The Department believes that high performance by OPOs should be rewarded in a way that does not disadvantage patients by compromising one of the fundamental objectives that the final rule is trying to achieve - namely broader sharing of organs. Therefore, the Department encourages the OPTN to develop and recommend to the Secretary policy incentives to reward high-performing OPOs. In addition, in response to longer-standing concerns, HHS' Health Care Financing Administration (HCFA) is reviewing the way it currently measures OPO performance.

Policies to Address Socioeconomic Barriers -- Some in the transplant community have expressed concern that the final rule would require transplant hospitals to make their own financial resources available to pay for transplant and follow-up care for patients unable to pay. However, this was not the intention of the April 2 final rule. The rule calls on the OPTN Board of Directors to recommend policies that would reduce inequities in access resulting from socioeconomic status and ensure that the registration fee itself does not represent a barrier to transplantation.

Registration Fees -- One commenter objected to Secretarial review of that portion of registration fees paid by OPTN members (and indirectly by patients and their insurers) that represents expenditures by the contractor that are not directly related to the tasks performed under the contracts with HHS. The final rule specifies that the Secretary has oversight of that portion of the registration fee directly related to operation of the OPTN.

Health Resources and Services Administration (HRSA)-HCFA Cooperation - A commenter noted the need for increased coordination between HRSA and HCFA on transplantation issues within their respective areas of responsibility. HRSA and HCFA have pursued several cooperative efforts to achieve increased organ donation, a goal of the Administration's National Organ and Tissue Donation Initiative, which was launched in December 1997. On June 22, 1998, HCFA published a final rule (42 CFR part 482) regarding Medicare Hospital Conditions of

Participation, which requires hospitals to refer all deaths and imminent deaths to local OPOs and conduct donation request training programs for appropriate staff representatives. In 1999, HRSA and HCFA jointly sponsored projects to encourage collaboration between hospitals and OPOs in effectively implementing this regulation. HCFA's responsibility for OPO performance standard establishment, certification and re-certification of OPOs, and OPO waiver request review involves close cooperation with HRSA to identify practices most likely to benefit donor families and transplant patients, and that impact current organ allocation policy. In addition, HCFA and HRSA are working together to enhance and better coordinate collection, reporting, and analysis of organ procurement and transplant data in an effort to assure optimum performance of the OPTN.

D. Data

Section 213 called for "timely and accurate program-specific information on the performance of transplant programs." The IOM report, in reviewing 68,000 medical records, made a significant contribution in the data area, although the report also cited the paucity of data available and recommended improved data collection and dissemination. In addition, UNOS recently has added Internet-based capability, both for providing information to physicians and the public and for collecting data from its members.

Finally, HHS has completed new transplant program-specific analyses that show varying outcomes for patients among different transplant hospitals. Department staff analyzed OPTN patient outcome data for liver and heart transplants with respect to three critical issues: 1) the likelihood that, having been listed as a transplant candidate, a patient will receive an organ within one year; 2) the likelihood that a patient will die within one year of listing while awaiting transplantation; and, 3) the likelihood that a patient will still be alive one year after listing, irrespective of whether he or she underwent a transplant procedure. After risk adjustment (i.e., adjustment for differences in the mix of patients' health status from program to program), the analyses revealed substantial differences in outcomes from one transplant program to another. The principal findings for liver transplants illustrate that:

- c ten percent of the programs have a standardized risk-adjusted rate of transplantation within one year of listing of 71 percent or more; whereas, for another ten percent of the programs, the rate is 25 percent or less;

- c the likelihood of dying within one year of listing while awaiting a transplant ranges from less than 8 percent to more than 22 percent; and
- c the likelihood of surviving one year after listing as a transplant candidate or a recipient ranges from approximately 65 percent to almost 86 percent.

The analogous values for heart transplants are 72 and 36 percent (transplantation within one year of listing), 9 and 23 percent (death within one year of listing while awaiting a transplant), 67 and 84 percent (survival for one year after listing irrespective of whether transplanted or not).

In the course of performing these analyses, Department staff identified gaps in the data currently collected by the Scientific Registry - e.g., additional clinical details about patients' conditions at the time of listing (which could improve risk adjustment) and additional data on clinical complications (which could help in assessing quality of life following transplantation). The Department has provided these analyses to UNOS and has encouraged it, in its management of the OPTN and its operation of the Scientific Registry, to broaden the scope of data collection and make increased use of program-specific performance analyses. The analyses are included in the *U.S. Department of Health and Human Services 1999 Report to Congress on the Scientific and Clinical Status of Organ Transplantation*.

II. Public Comments

Between April 2 and September 16, 1998, we received a total of approximately 2,500 comments on the final rule. (Letters with petitions or with form letters attached were counted as one comment. HHS received a total of approximately 20,000 form letters.) The majority of the comments reflected issues addressed in "Clarifications" above. This document includes changes intended to make these issues clear. Other issues raised by commenters were discussed in the meetings conducted this year pursuant to section 213 of the Appropriation Act, and they are also outlined above.

III. Changes in the Regulatory Text

As a result of the comments received, the Department has made several modifications to the final rule published on April 2, 1998. Some changes have been made to clarify the regulatory language. Other revisions to the regulatory text add provisions or modify requirements from the previously published final rule.

1. Definition of Organ

The Department has deleted bone marrow from the definition of organ in § 121.2 because it falls within the scope of a different statutory authority. Although the NOTA refers to bone marrow for purposes of the Scientific Registry, subsequent legislation established a separate program to address "unrelated" bone marrow transplants. A commenter recommended that the definition be expanded to include intestine, stomach, or a collection of human cells that perform a vital function of an organ, including any organ containing vasculature that carries blood after transplantation. In the Preamble to the 1998 rule, the Department stated: "The inclusion of other organs, such as the stomach and intestines, not only would have an impact on other requirements in these regulations such as the development of allocation policies, certification of designated transplant programs, and establishment of training requirements but also would affect OPO requirements to procure these organs in accordance with HCFA rules. Thus, the Department believes it would be premature for this rule to specify other organs in addition to those already named. Instead, the Department will direct the OPTN contractor to consider which organs or parts of organs, if any, should be subject to OPTN policies, and to submit recommendations to the Secretary." The Department's position on this issue remains unchanged.

2. National List

The term "national list" has been replaced with "waiting list" in § 121.2, and throughout the final rule. The term "national list" was incorporated into the regulation to reflect statutory language in section 372 of the Public Health Service (PHS) Act, 42 U.S.C. 274, which requires the OPTN to "establish a national list of individuals who need organs." Current OPTN allocation convention derives subordinate lists from a single database and current OPTN policy allocates zero-antigen mismatched kidneys nationally, due to scientifically demonstrated improvements in patient and graft survival resulting from this policy. Furthermore, ischemic times and patient outcomes make such an approach appropriate in the case of zero-antigen mismatched kidneys. If supported by scientific evidence, the Department has no objection to this approach.

3. Composition of OPTN Board of Directors

The Department wishes to ensure adequate patient, donor and family representation on the OPTN Board of Directors, while giving the OPTN sufficient flexibility to constitute a balanced and effective Board. Thus the Department has included a requirement under § 121.3(a) that the Board of Directors shall include at least 25 percent transplant candidates, transplant recipients, organ donors,

and family members. In response to comments, the Department also has revised §121.3(a)(1) to enable the OPTN to govern itself with greater flexibility than was provided by the 1998 rule. The revised language maintains the requirement that the Board of Directors include representatives of OPOs, transplant centers, voluntary health associations, transplant coordinators, histocompatibility experts, other non-physician transplant professionals, and the general public, but does not mandate a specific number of members from each category. The Secretary believes that the less prescriptive language in this revision will better allow the OPTN itself to determine the appropriate size of, and representation on, its Board of Directors, while achieving a balance among physician, patient, donor, family and other representatives.

Section 121.3(a)(2) has been revised. That paragraph prohibited those Board members who were identified as transplant recipients, transplant candidates, organ donors, family members, or members of the general public to be employees of, or have similar relationships with, specified categories of institutional members required to be on the Board. The revised paragraph is more flexible, as described more fully above.

As discussed above, §121.3(a) has been revised to require that approximately 50 percent of the Board members be transplant surgeons or transplant physicians, rather than the language of the April 2, 1998, rule requiring no more than 50 percent, and that at least 25 percent of its members be transplant candidates, transplant recipients, organ donors, and family members. The comparable requirements for the Executive Committee of the Board have been similarly revised. Transplant physicians or transplant surgeons elected to the Board or Executive Committee under other categories must be counted toward the requirements of these paragraphs of the final rule.

Furthermore, the requirement for a two year term for Board members in former §121.3(a)(4) has been deleted. Board members have diverse backgrounds and will require different periods of time to become familiar with the complex issues coming before the Board. Thus, we believe that it is appropriate for the OPTN to determine for itself the length of the term for Board members, subject to Departmental review.

4. Socioeconomic Issues

As articulated in the April 2, 1998, rule, the Department is concerned that all patients in the country have access to transplantation and encourages the OPTN to work toward this goal. Several members of the transplant community,

however, commented that the provisions of §121.4 addressing socioeconomic issues would require transplant hospitals to make their own financial resources available to pay for transplantation and follow-up care for patients unable to pay. In response to these comments, the Department has revised this section to specify that paragraph (a)(3)(i) refers only to the registration fee and has revised paragraph (a)(3)(ii) to clarify that resources for patients unable to pay should be sought from all available sources.

5. Secretarial Review of OPTN Policies

In response to comments asking which OPTN policies are to be submitted to the Secretary, the Department has modified the language of §121.4(b)(2) to provide that the Board of Directors is required to provide the Secretary with proposed policies that the OPTN recommends be enforceable under §121.10 (including allocation policies) and others as specified by the Secretary. As discussed above, the rule has been revised to adopt the IOM's recommendation that the Advisory Committee assist the Secretary in reviewing OPTN policies and practices as well as to indicate the purposes of the Secretary's review.

The timing requirement has also been changed from 30 days to 60 days before implementation of the proposed policy to provide a more realistic estimate of the time required for review by the Advisory Committee and the public, should such review be necessary.

6. Registration Fee

One commenter objected to Secretarial review of the patient registration fee, maintaining that this fee is paid voluntarily by OPTN members for the services provided to them by the contractor. The Department agrees that a portion of the current fee represents a voluntary payment by OPTN members to the contractor for services outside the direct operation of the OPTN on behalf of patients, while another portion represents the payment provided by patients and their insurers for the operation of the OPTN system itself. Consequently, the Department has modified the language of §121.5(c) to indicate that the portion of the registration fee subject to Secretarial oversight is that portion directly related to operation of the OPTN; any other fee may only be charged on a voluntary basis to OPTN members. In this regard, the Department would interpret the "reasonable costs" for operating the OPTN to include additional costs of compliance under §121.8(a)(7) and reviews and enforcement under §121.10.

7. Human Immunodeficiency Virus (HIV)

Commenters suggested revising the language of §121.6(b) to authorize transplantation of organs from HIV positive donors to HIV positive recipients. The Department has revised §121.6(b) to reflect the language of the statute. We note, however, that HCFA regulations governing OPOs, at 42 CFR 486.306(q), require OPOs to screen donors to “[e]nsure that appropriate donor screening and infection tests, consistent with the OPTN standards and the CDC [Centers for Disease Control and Prevention] guidelines ... are performed ... to prevent the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.” The OPO regulations require that OPO donor screening meet the two thresholds of the OPTN standards as well as the CDC guidelines. OPOs must comply with the CDC “Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs” as appended to the regulations for OPOs (see 42 CFR part 486, Subpart G, Appendix A). As a result, the OPO regulations will still preclude acquisition of an organ from an HIV-positive donor for transplantation. The OPTN may propose standards permitting such transplantation to the Secretary for consideration and potential change in existing CDC guidelines.

8. Criteria for Listing Patients

The 1998 rule set as a performance goal that the OPTN standardize objective and measurable medical criteria for including patients on the waiting list. In drafting the language of that section, the Department expected that the criteria developed for adding patients to the waiting list would inherently contain criteria for removing patients from the list. Commenters pointed out that the rule should be specific in this respect. The Department adopted this suggested clarification in §121.8(b)(1).

9. Organ Allocation

The Department received many comments on this section, especially former § 121.8(a). We have reorganized this entire section for clarity and addressed points raised by the IOM as well as several issues raised by commenters. Some commenters asked that we clarify the OPTN’s ability to have different allocation policies for different types of organs (or combinations of organs) to be transplanted. Language to this effect is now found in §121.8(a)(4). The Department wishes to emphasize that this means that the OPTN may take a different approach in defining priority ranking under §121.8(b)(2) for organs like kidneys where the technology of renal dialysis permits some flexibility in determining the timing of a transplant. Similarly, a different approach may also be taken where such “rescue”

techniques are available for other organs. Such alternatives may be used, consistent with sound medical judgment.

Other commenters suggested that the concepts of using sound medical judgment, avoidance of futile transplants or wastage of organs, and promotion of the efficient use of organs should be applicable to all the performance goals. Language adopting this suggestion is now found in §121.8(a)(5).

We have added to §121.8(a)(5) a provision that allocation policy seek to promote patient access to transplants, an issue Congress asked the IOM to address. As discussed above, we have also added at §121.8(a)(7) language to promote compliance with and enforcement of approved allocation policies.

We have revised the discussion of medical urgency now found in §121.8(b)(2). We have made clear that the need to rank patients or categories of patients in order of decreasing medical urgency only applies to otherwise medically appropriate candidates for transplants. This is consistent with the provisions found in §121.8(a) that require allocation policies be developed in accordance with sound medical judgment and avoidance of futile transplants and organ wastage.

Some commenters suggested that the rule was unclear as to how “medical urgency” applies to kidney allocation policy. We revised this section in response to comments that the term “status categories,” as currently used for liver and heart patients, is not used for kidney patients. (Instead, a point system is used to rank patients when an organ becomes available.) The use of the term “patients or categories of patients” in this section makes clear that ranking patients rather than categories of patients is permitted under this rule. As discussed above, we intend for ranking to be applied in the context of the factors listed in §121.8(a), especially in accordance with sound medical judgment. Therefore, we believe that there may well be different approaches to kidney allocation policy than those for other types of organs, perhaps along the lines of the current policies, which take into account such factors as immunologic compatibility between the donor and patient, whether the patient’s immune system is highly sensitized, and other medical factors.

Commenters suggested that the Department closely monitor the changes to allocation policies made after the initial reviews required under this section to ensure that the new policies are achieving the desired improvements in the allocation system. The Department intends to monitor the effects of these changes closely and in consultation with

the OPTN. In addition to this monitoring and consultation, the Department will formally determine whether further changes are necessary six months and 12 months after the changes to allocation policies made after the initial reviews go into effect.

Finally, as discussed above, we have given the OPTN additional flexibility with respect to performance indicators, including waiting times, in response both to comments received and the IOM report.

The Department wishes to emphasize, however, that these changes are not intended to limit the ability of the OPTN to address special situations such as the unique needs of young children.

10. Department of Veterans Affairs Hospitals

The term “Dean’s Committee” has been deleted from §121.9(a)(3), as this is not a term currently used by the Department of Veterans Affairs. Currently, the Department of Veterans Affairs, Veterans Health Administration, designates specific VA medical centers to carry out organ transplantation. To cover the possibility that transplants may also be carried out in other Federal hospitals, as well as those owned and operated by the Department of Defense (DoD), transplant programs in DoD or other Federal hospitals have been added to those eligible to receive organs for transplantation under §121.9(a).

11. Enforcement

Section 121.10(c)(1) has been edited to clarify that appropriate enforcement action may include termination of a transplant program’s reimbursement under Medicare and Medicaid. In addition, the Department wishes to clarify that the regulation permits the OPTN to develop policies that will contain lesser or intermediate level sanctions that may be taken by the OPTN, but these policies must first be approved by the Secretary in order for them to be enforceable.

12. Reporting Requirements

Section 121.11(b)(2) has been amended to include transplant program costs among the items to be reported by transplant hospitals to the OPTN and the Secretary. Although the language in the previously published final rule was sufficiently broad to permit the Secretary to specify that cost information be submitted, it was felt that its specific inclusion in the rule would ensure that such information would be made available on a timely basis when requested, consistent with section 213. Because of the difficulty in

defining costs for these purposes, the Department will accept measures of resource utilization.

13. Effect of the Regulation on State Laws (former §121.12)

The inclusion of §121.12 in the 1998 regulation was intended to be consonant with longstanding Constitutional principles regarding the relationship between the Federal and State governments. It reflected the HHS belief that Congress intended the statutory scheme it established under NOTA to result “in the nationwide distribution of organs equitably among transplant patients.” Section 372(b)(2)(D) of the Public Health Service Act. Nevertheless, because the Department views this result as flowing from the statutory scheme, the section of the regulation articulating the Department’s views on the matter is unnecessary as a legal matter. Accordingly, §121.12 has been removed.

14. Advisory Committee on Organ Transplantation

The Department intends to implement the recommendation of the IOM, as discussed above, to create an independent, multidisciplinary scientific advisory board which will assist the Secretary in, “ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible.” Constitution of such an advisory committee and its consultation by the Secretary, as appropriate, in the words of the IOM, “would also enhance public confidence in the integrity and effectiveness of the system.” The Department has added a new §121.12 to provide for the establishment of an Advisory Committee on Organ Transplantation. The Committee, to be established in accordance with the Federal Advisory Committee Act [5 U.S.C. App.], will be available to the Secretary to provide comments on proposed OPTN policies and other matters related to transplantation. The Committee will be composed of individuals drawn from diverse backgrounds such as health care public policy, transplantation medicine and surgery, non-physician transplant professions, biostatistics, immunology, health economics, epidemiology, bioethics, and law. As part of this process of establishing the Committee, the Secretary intends to solicit nominations for Committee members from the transplant community and the general public.

IV. Impact Analyses

We have examined the impact of this amendatory language as required by Executive Order 12866, section 202 of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) and the Regulatory Flexibility Act (RFA) (Public Law

96-354). Executive Order 12866 directs agencies to assess costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize benefits. The Unfunded Mandates Reform Act of 1995 also requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may mandate an annual expenditure by State, local, or tribal governments of \$100 million or more.

List of Subjects in 42 CFR part 121

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), if an action has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the effects on small business entities and analyze regulatory options that could lessen the impact of the rule.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any regulation that may have a significant impact on the operations of a substantial number of small rural hospitals.

The amendatory language set forth in this document makes no changes that have a significant economic effect on State, local or tribal governments, hospitals or patients; therefore, we certify that no additional regulatory analysis is required. We have also concluded, based on the findings of the Institute of Medicine and the General Accounting Office under section 213(b), discussed earlier in this Preamble, and the Secretary certifies, that this amendatory language would not have a significant economic impact on a substantial number of small entities; therefore, a regulatory flexibility analysis is not required.

We are also not preparing a rural impact statement since we have determined, and the Secretary certifies, that this amendatory language would not have a significant impact on the operations of a substantial number of small rural hospitals.

The earlier analyses from the April 2, 1998, final rule remain applicable to that rule and are not altered by these amendments.

Healthcare, Hospitals, Organ transplantation, Reporting and
recordkeeping requirements.

Dated:

Administrator
Health Resources and Services Administration

Approved:

Secretary

**ORGAN PROCUREMENT AND TRANSPLANTATION
NETWORK (OPTN) FINAL RULE AS REVISED BY
AMENDMENTS**

42 CFR part 121 has been amended to read as follows:
Part 121-Organ Procurement and Transplantation Network
Sec.

- 121.1 Applicability.
- 121.2 Definitions.
- 121.3 The OPTN.
- 121.4 OPTN Policies; Secretarial Review and Appeals.
- 121.5 Listing requirements.
- 121.6 Organ procurement.
- 121.7 Identification of organ recipient.
- 121.8 Allocation of organs.
- 121.9 Designated transplant program requirements.
- 121.10 Reviews, evaluation, and enforcement.
- 121.11 Record maintenance and reporting requirements.
- 121.12 Advisory Committee on Organ Transplantation.

Authority: Sections 215, 371-376 of the Public Health Service Act (42 U.S.C. 216, 273-274d); sections 1102, 1106, 1138 and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b-8 and 1395hh).

§ 121.1 Applicability.

(a) The provisions of this part apply to the operation of the Organ Procurement and Transplantation Network (OPTN) and to the Scientific Registry.

(b) In accordance with section 1138 of the Social Security Act, hospitals in which organ transplants are performed and which participate in the programs under titles XVIII or XIX of the Social Security Act, and organ procurement organizations designated under section 1138(b) of the Social Security Act, are subject to the requirements of this part.

§ 121.2 Definitions.

As used in this part-

Act means the Public Health Service Act, as amended.

Designated transplant program means a transplant program that has been found to meet the requirements of §121.9.

Family member means a family member of a transplant candidate, transplant recipient, or organ donor.

OPTN computer match program means a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the waiting list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).

Organ means a human kidney, liver, heart, lung, or pancreas.

Organ donor means a human being who is the source of an organ for transplantation into another human being.

Organ procurement organization or OPO means an entity so designated by the Secretary under section 1138(b) of the Social Security Act.

Organ procurement and transplantation network or OPTN means the network established pursuant to section 372 of the Act.

Potential transplant recipient or potential recipient means a transplant candidate who has been ranked by the OPTN computer match program as the person to whom an organ from a specific cadaveric organ donor is to be offered.

Scientific Registry means the registry of information on transplant recipients established pursuant to section 373 of the Act.

Secretary means the Secretary of Health and Human Services and any official of the Department of Health and Human Services to whom the authority involved has been delegated.

Transplant candidate means an individual who has been identified as medically suited to benefit from an organ transplant and has been placed on the waiting list by the individual's transplant program.

Transplant hospital means a hospital in which organ transplants are performed.

Transplant physician means a physician who provides non-surgical care and treatment to transplant patients before and after transplant.

Transplant program means a component within a transplant hospital which provides transplantation of a particular type of organ.

Transplant recipient means a person who has received an organ transplant.

Transplant surgeon means a physician who provides surgical care and treatment to transplant recipients.

Waiting list means the OPTN computer-based list of transplant candidates.

§ 121.3 The OPTN.

(a) Organization of the OPTN. (1) The OPTN shall establish a Board of Directors of whatever size the OPTN determines appropriate. The Board of Directors shall include:

(i) Approximately 50 percent transplant surgeons or transplant physicians;

(ii) At least 25 percent transplant candidates, transplant recipients, organ donors and family members. These members should represent the diversity of the population of transplant candidates, transplant recipients,

organ donors and family members served by the OPTN including, to the extent practicable, the minority and gender diversity of this population. These members shall not be employees of, or have a similar relationship with OPOs, transplant centers, voluntary health organizations, transplant coordinators, histocompatibility experts, or other non-physician transplant professionals; however, the Board may waive this requirement for not more than 50 percent of these members; and

(iii) Representatives of OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public.

(2) The Board of Directors shall elect an Executive Committee from the membership of the Board. The Executive Committee shall include at least one general public member, one OPO representative, approximately 50 percent transplant surgeons and transplant physicians, and at least 25 percent transplant candidates, transplant recipients, organ donors, and family members.

(3) The Board of Directors shall appoint an Executive Director of the OPTN. The Executive Director may be reappointed upon the Board's determination that the responsibilities of this position have been accomplished successfully.

(4) The Board of Directors shall establish such other committees as are necessary to perform the duties of the OPTN. Committees established by the Board of Directors shall include:

(i) Representation by transplant coordinators, organ procurement organizations, and transplant hospitals, and at least one transplant candidate, transplant recipient, organ donor or family member; and

(ii) To the extent practicable, minority and gender representation reflecting the diversity of the population of transplant candidates, transplant recipients, organ donors and family members served by the OPTN.

(b) Membership of the OPTN. (1) The OPTN shall admit and retain as members the following:

(i) All organ procurement organizations;

(ii) Transplant hospitals participating in the Medicare or Medicaid programs; and

(iii) Other organizations, institutions, and individuals that have an interest in the fields of organ donation or transplantation.

(2) To apply for membership in the OPTN:

(i) An OPO shall provide to the OPTN the name and address of the OPO, and the latest year of designation under section 1138(b) of the Social Security Act;

(ii) A transplant hospital shall provide to the OPTN the name and address of the hospital, a list of its transplant programs by type of organ; and

(iii) Any other organization, institution, or individual eligible under paragraph (c)(1)(iii) of this section shall demonstrate to the OPTN an interest in the fields of organ donation or transplantation.

(3) The OPTN shall accept or reject as members entities or individuals described in paragraph (c)(1)(iii) of this section within 90 days.

(4) Applicants rejected for membership in the OPTN may appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may:

(i) Deny the appeal; or

(ii) Direct the OPTN to take action consistent with the Secretary's response to the appeal.

(c) Corporate status of the OPTN. (1) The OPTN shall be a private, not-for-profit entity.

(2) The requirements of this section do not apply to any parent, sponsoring, or affiliated organization of the OPTN, or to any activities of the contracting organization that are not integral to the operation of the OPTN. Such an organization is free to establish its own corporate procedures.

(3) No OPTN member is required to become a member of any organization that is a parent, sponsor, contractor, or affiliated organization of the OPTN, to comply with the by-laws of any such organization, or to assume any corporate duties or obligations of any such organization.

(d) Effective date. The organization designated by the Secretary as the OPTN shall have until June 30, 2000, or six months from its initial designation as the OPTN, whichever is later, to meet the requirements of this section, except that the Secretary may extend such period for good cause.

§ 121.4 OPTN policies: Secretarial review and appeals.

(a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act and the Secretary's contract for the operation of the OPTN, including:

(1) Policies for the equitable allocation of cadaveric organs in accordance with §121.8;

(2) Policies, consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases;

(3) Policies that reduce inequities resulting from socioeconomic status, including, but not limited to:

(i) Ensuring that payment of the registration fee is not a barrier to listing for patients who are unable to pay the fee;

(ii) Procedures for transplant hospitals to make reasonable efforts to obtain from all available sources, financial resources for patients unable to pay such that these patients have an opportunity to obtain a transplant and necessary follow-up care;

(iii) Recommendations to private and public payers and service providers on ways to improve coverage of organ transplantation and necessary follow-up care; and

(iv) Reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities;

(4) Policies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs as required by §121.9;

(5) Policies for nominating officers and members of the Board of Directors; and

(6) Policies on such other matters as the Secretary directs.

(b) The Board of Directors shall:

(1) Provide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and adopting policies for implementation by the OPTN; and

(2) Provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies it recommends to be enforceable under §121.10 (including allocation policies). These policies will not be enforceable until approved by the Secretary. The Board of Directors shall also provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies on such other matters as the Secretary directs. The Secretary will refer significant proposed policies to the Advisory Committee on Organ Transplantation established under §121.12, and publish them in the Federal Register for public comment. The Secretary also may seek the advice of the Advisory Committee on Organ Transplantation established under §121.12 on other proposed policies, and publish them in the Federal Register for public comment. The Secretary will determine whether the proposed policies are consistent with the National Organ Transplant Act and this part, taking into account the views of the Advisory Committee and public comments. Based on this review, the Secretary may provide comments to the OPTN. If the Secretary concludes that a proposed policy is inconsistent with the National Organ Transplant Act or this part, the Secretary may direct the OPTN to revise the proposed policy consistent with the Secretary's direction. If the OPTN does not revise the proposed policy in a timely manner, or if the Secretary concludes that the proposed revision is inconsistent with the National Organ Transplant Act or this part, the Secretary may take such

other action as the Secretary determines appropriate, but only after additional consultation with the Advisory Committee on the proposed action.

(c) The OPTN Board of Directors shall provide the membership and the Secretary with copies of its policies as they are adopted, and make them available to the public upon request. The Secretary will publish lists of OPTN policies in the Federal Register, indicating which ones are enforceable under §121.10 or subject to potential sanctions of section 1138 of the Social Security Act. The OPTN shall also continuously maintain OPTN policies for public access on the Internet, including current and proposed policies.

(d) Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN. Any such comments shall include a statement of the basis for the comments. The Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments related to OPTN policies or practices. Policies or practices that are the subject of critical comments remain in effect during the Secretary's review, unless the Secretary directs otherwise based on possible risk to the health of patients or to public safety. The Secretary will consider the comments in light of the National Organ Transplant Act and the regulations under this part and may consult with the Advisory Committee on Organ Transplantation established under §121.12. After this review, the Secretary may:

(1) Reject the comments;

(2) Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments; or,

(3) Take such other action as the Secretary determines appropriate.

(e) The OPTN shall implement policies and shall:

(1) Provide information to OPTN members about these policies and the rationale for them; and

(2) Update policies developed in accordance with this section to accommodate scientific and technological advances.

§ 121.5 Listing requirements.

(a) A transplant hospital which is an OPTN member may list individuals, consistent with the OPTN's criteria under §121.8(b)(1), only for a designated transplant program.

(b) Transplant hospitals shall assure that individuals are placed on the waiting list as soon as they are determined to be candidates for transplantation. The OPTN shall advise transplant hospitals of the information needed for such listing.

(c) An OPTN member shall pay a registration fee to the OPTN for each transplant candidate it places on the waiting list. The amount of such fee shall be calculated to cover (together with contract funds awarded by the Secretary) the reasonable costs of operating the OPTN and shall be determined by the OPTN with the approval of the Secretary. No less often than annually, and whether or not a change is proposed, the OPTN shall submit to the Secretary a statement of its proposed registration fee, together with such supporting information as the Secretary finds necessary to determine the reasonableness or adequacy of the fee schedule and projected revenues. This submission is due at least three months before the beginning of the OPTN's fiscal year. The Secretary will approve, modify, or disapprove the amount of the fee within a reasonable time of receiving the OPTN's submission.

§ 121.6 Organ procurement. The suitability of organs donated for transplantation shall be determined as follows:

- (a) Tests. An OPTN member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN.
- (b) HIV. The OPTN shall adopt and use standards for preventing the acquisition of organs from individuals known to be infected with human immunodeficiency virus.
- (c) Acceptance criteria. Transplant programs shall establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated.

§ 121.7 Identification of organ recipient.

(a) List of potential transplant recipients. (1) An OPTN member procuring an organ shall operate the OPTN computer match program within such time as the OPTN may prescribe to identify and rank potential recipients for each cadaveric organ procured.

(2) The rank order of potential recipients shall be determined for each cadaveric organ using the organ specific allocation criteria established in accordance with §121.8.

(3) When a donor or donor organ does not meet a transplant program's donor acceptance criteria, as established under §121.6(c), transplant candidates of that program shall not be ranked among potential recipients of that organ and shall not appear on a roster of potential recipients of that organ.

(b) Offer of organ for potential recipients. (1) Organs shall be offered for potential recipients in accordance with

policies developed under §121.8 and implemented under §121.4.

(2) Organs may be offered only to potential recipients listed with transplant programs having designated transplant programs of the same type as the organ procured.

(3) An organ offer is made when all information necessary to determine whether to transplant the organ into the potential recipient has been given to the transplant hospital.

(4) A transplant program shall either accept or refuse the offered organ for the designated potential recipient within such time as the OPTN may prescribe. A transplant program shall document and provide to the OPO and to the OPTN the reasons for refusal and shall maintain this document for one year.

(c) Transportation of organ to potential recipient. (1) Transportation. The OPTN member that procures a donated organ shall arrange for transportation of the organ to the transplant hospital.

(2) Documentation. The OPTN member that is transporting an organ shall assure that it is accompanied by written documentation of activities conducted to determine the suitability of the organ donor and shall maintain this document for one year.

(3) Packaging. The OPTN member that is transporting an organ shall assure that it is packaged in a manner that is designed to maintain the viability of the organ.

(d) Receipt of an organ. Upon receipt of an organ, the transplant hospital responsible for the potential recipient's care shall determine whether to proceed with the transplant. In the event that an organ is not transplanted into the potential recipient, the OPO which has a written agreement with the transplant hospital must offer the organ for another potential recipient in accordance with paragraph (b)(2) of this section.

(e) Wastage. Nothing in this section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. The transplant program shall notify the OPTN and the OPO which made the organ offer of the circumstances justifying each such action within such time as the OPTN may prescribe.

§ 121.8 Allocation of organs.

(a) Policy development. The Board of Directors established under §121.3 shall develop, in accordance with the policy development process described in §121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:

- (1) Shall be based on sound medical judgment;

(2) Shall seek to achieve the best use of donated organs;

(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4), (d) and (e);

(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and

(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

(b) Allocation performance goals. Allocation policies shall be designed to achieve equitable allocation of organs among patients consistent with paragraph (a) of this section through the following performance goals:

(1) Standardizing the criteria for determining suitable transplant candidates through the use of minimum criteria (expressed, to the extent possible, through objective and measurable medical criteria) for adding individuals to, and removing candidates from, organ transplant waiting lists;

(2) Setting priority rankings expressed, to the extent possible, through objective and measurable medical criteria, for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings shall be ordered from most to least medically urgent (taking into account, in accordance with paragraph (a) of this section, and in particular in accordance with sound medical judgment, that life sustaining technology allows alternative approaches to setting priority ranking for patients). There shall be a sufficient number of categories (if categories are used) to avoid grouping together patients with substantially different medical urgency;

(3) Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency; and

(4) Applying appropriate performance indicators to assess transplant program performance under paragraphs (c)(2)(i) and (c)(2)(ii) of this section and reducing the inter-transplant program variance to as small as can reasonably

be achieved in any performance indicator under paragraph (c)(2)(iii) of this section as the Board determines appropriate, and under paragraph (c)(2)(iv) of this section. If the performance indicator ~~Awaiting time in status~~ is used for allocation purposes, the OPTN shall seek to reduce the inter-transplant program variance in this indicator, as well as in other selected performance indicators, to as small as can reasonably be achieved, unless to do so would result in transplanting less medically urgent patients or less medically urgent patients within a category of patients.

(c) Allocation performance indicators. (1) Each organ-specific allocation policy shall include performance indicators. These indicators must measure how well each policy is:

(i) Achieving the performance goals set out in paragraph (b) of this section; and

(ii) Giving patients, their families, their physicians, and others timely and accurate information to assess the performance of transplant programs.

(2) Performance indicators shall include:

(i) Baseline data on how closely the results of current allocation policies approach the performance goals established under paragraph (b) of this section;

(ii) With respect to any proposed change, the amount of projected improvement in approaching the performance goals established under paragraph (b) of this section;

(iii) Such other indicators as the Board may propose and the Secretary approves; and

(iv) Such other indicators as the Secretary may require.

(3) For each organ-specific allocation policy, the OPTN shall provide to the Secretary data to assist the Secretary in assessing organ procurement and allocation, access to transplantation, the effect of allocation policies on programs performing different volumes of transplants, and the performance of OPOs and the OPTN contractor. Such data shall be required on performance by organ and status category, including program-specific data, OPO-specific data, data by program size, and data aggregated by organ procurement area, OPTN region, the Nation as a whole, and such other geographic areas as the Secretary may designate. Such data shall include the following measures of inter-transplant program variation: risk-adjusted total life-years pre- and post-transplant, risk-adjusted patient and graft survival rates following transplantation, risk-adjusted waiting time and risk-adjusted transplantation rates, as well as data regarding patients whose status or medical urgency was misclassified and patients who were inappropriately kept off a waiting list or retained on a waiting list. Such data shall cover such intervals of time, and be presented using

confidence intervals or other measures of variance, as may be required to avoid spurious results or erroneous interpretation due to small numbers of patients covered.

(d) Transition patient protections. (1) General. When the OPTN revises organ allocation policies under this section, it shall consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies. The transition procedures shall be transmitted to the Secretary for review together with the revised allocation policies.

(2) Special rule for initial revision of liver allocation policies. When the OPTN transmits to the Secretary its initial revision of the liver allocation policies, as directed by paragraph (e)(1) of this section, it shall include transition procedures that, to the extent feasible, treat each individual on the waiting list and awaiting transplantation on October 20, 1999 no less favorably than he or she would have been treated had the revised liver allocation policies not become effective. These transition procedures may be limited in duration or applied only to individuals with greater than average medical urgency if this would significantly improve administration of the list or if such limitations would be applied only after accommodating a substantial preponderance of those disadvantaged by the change in the policies.

(e) Deadlines for initial reviews. (1) The OPTN shall conduct an initial review of existing allocation policies and, except as provided in paragraph (e)(2) of this section, no later than November 16, 2000 shall transmit initial revised policies to meet the requirements of paragraphs (a) and (b) of this section, together with supporting documentation to the Secretary for review in accordance with §121.4.

(2) No later than February 15, 2000 the OPTN shall transmit revised policies and supporting documentation for liver allocation to meet the requirements of paragraphs (a) and (b) of this section to the Secretary for review in accordance with §121.4. The OPTN may transmit these materials without seeking further public comment under §121.4(b).

(f) Secretarial review of policies, performance indicators, and transition patient protections. The OPTN's transmittal to the Secretary of proposed allocation policies and performance indicators shall include such supporting material, including the results of model-based computer simulations, as the Secretary may require to assess the likely effects of policy changes and as are necessary to demonstrate that the proposed policies comply with the performance indicators and transition procedures of paragraphs (c) and (d) of this section.

(g) Variances. The OPTN may develop, in accordance with §121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of §121.4.

(h) Directed donation. Nothing in this section shall prohibit the allocation of an organ to a recipient named by those authorized to make the donation.

§ 121.9 Designated transplant program requirements.

(a) To receive organs for transplantation, a transplant program in a hospital that is a member of the OPTN shall abide by these rules and shall:

(1) Be a transplant program approved by the Secretary for reimbursement under Medicare; or

(2) Be an organ transplant program which has adequate resources to provide transplant services to its patients and agrees promptly to notify the OPTN and patients awaiting transplants if it becomes inactive and which:

(i) Has letters of agreement or contracts with an OPO;

(ii) Has on site a transplant surgeon qualified in accordance with policies developed under §121.4;

(iii) Has on site a transplant physician qualified in accordance with policies developed under §121.4;

(iv) Has available operating and recovery room resources, intensive care resources and surgical beds and transplant program personnel;

(v) Shows evidence of collaborative involvement with experts in the fields of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility, and immunogenetics and, as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support;

(vi) Has immediate access to microbiology, clinical chemistry, histocompatibility testing, radiology, and blood banking services, as well as the capacity to monitor treatment with immunosuppressive drugs; and

(vii) Makes available psychiatric and social support services for transplant candidates, transplant recipients, and their families; or

(3) Be a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.

(b) To apply to be a designated transplant program, transplant programs shall provide to the OPTN such

documents as the OPTN may require which show that they meet the requirements of § 121.9(a)(1), (2), or (3).

(c) The OPTN shall, within 90 days, accept or reject applications to be a designated transplant program.

(d) Applicants rejected for designation may appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may:

(1) Deny the appeal; or

(2) Direct the OPTN to take action consistent with the Secretary's response to the appeal.

§ 121.10 Reviews, evaluation, and enforcement.

(a) Review and evaluation by the Secretary. The Secretary or her/his designee may perform any reviews and evaluations of member OPOs and transplant programs which the Secretary deems necessary to carry out her/his responsibilities under the Public Health Service Act and the Social Security Act.

(b) Review and evaluation by the OPTN. (1) The OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of:

(i) Reviewing applications submitted under § 121.3(c) for membership in the OPTN;

(ii) Reviewing applications submitted under § 121.9(b) to be a designated transplant program; and

(iii) Conducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies.

(2) Upon the approval of the Secretary, the OPTN shall furnish review plans and procedures, including survey instruments and a description of data systems, to each member OPO and transplant hospital. The OPTN shall furnish any revisions of these documents to member OPOs and hospitals, after approval by the Secretary, prior to their implementation.

(3) At the request of the Secretary, the OPTN shall conduct special reviews of OPOs and transplant programs, where the Secretary has reason to believe that such entities may not be in compliance with these rules or OPTN policies or may be acting in a manner which poses a risk to the health of patients or to public safety. The OPTN shall conduct these reviews in accordance with such schedules as the Secretary specifies and shall make periodic reports to the Secretary of progress on such reviews and on other reviews conducted under the requirements of this paragraph.

(4) The OPTN shall notify the Secretary in a manner prescribed by the Secretary within 3 days of all committee and Board of Directors meetings in which transplant hospital and OPO compliance with these regulations or OPTN policies is considered.

(c) Enforcement of OPTN rules. (1) OPTN recommendations. The Board of Directors shall advise the Secretary of the results of any reviews and evaluations conducted under paragraph (b)(1)(iii) or paragraph (b)(3) of this section which, in the opinion of the Board, indicate noncompliance with these rules or OPTN policies, or indicate a risk to the health of patients or to the public safety, and shall provide any recommendations for appropriate action by the Secretary. Appropriate action may include removal of designation as a transplant program under § 121.9, termination of a transplant hospital's participation in Medicare or Medicaid, termination of a transplant hospital's reimbursement under Medicare and Medicaid, termination of an OPO's reimbursement under Medicare and Medicaid, if the noncompliance is with a policy designated by the Secretary as covered by section 1138 of the Social Security Act, or such other compliance or enforcement measures contained in policies developed under § 121.4.

(2) Secretary's action on recommendations. Upon the Secretary's review of the Board of Directors' recommendations, the Secretary may:

(i) Request further information from the Board of Directors or the alleged violator, or both;

(ii) Decline to accept the recommendation;

(iii) Accept the recommendation, and notify the alleged violator of the Secretary's decision; or

(iv) Take such other action as the Secretary deems necessary.

§ 121.11 Record maintenance and reporting requirements.

(a) Record maintenance. Records shall be maintained and made available subject to OPTN policies and applicable limitations based on personal privacy as follows:

(1) The OPTN and the Scientific Registry, as appropriate, shall:

(i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;

(ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients;

(iii) Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested; and

(iv) In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently.

(2) Organ procurement organizations and transplant programs.

(i) Maintenance of records. All OPOs and transplant programs shall maintain such records pertaining to each potential donor identified, each organ retrieved, each recipient transplanted and such other transplantation-related matters as the Secretary deems necessary to carry out her/his responsibilities under the Act. The OPO or transplant program shall maintain these records for seven years.

(ii) Access to facilities and records. OPOs and transplant hospitals shall permit the Secretary and the Comptroller General, or their designees, to inspect facilities and records pertaining to any aspect of services performed related to organ donation and transplantation.

(b) Reporting requirements. (1) The OPTN and the Scientific Registry, as appropriate, shall:

(i) In addition to special reports which the Secretary may require, submit to the Secretary a report not less than once every fiscal year on a schedule prescribed by the Secretary. The report shall include the following information in a form prescribed by the Secretary:

(A) Information that the Secretary prescribes as necessary to assess the effectiveness of the Nation's organ donation, procurement and transplantation system;

(B) Information that the Secretary deems necessary for the report to Congress required by Section 376 of the Act; and,

(C) Any other information that the Secretary prescribes.

(ii) Provide to the Scientific Registry data on transplant candidates and recipients, and other information that the Secretary deems appropriate. The information shall be provided in the form and on the schedule prescribed by the Secretary;

(iii) Provide to the Secretary any data that the Secretary requests;

(iv) Make available to the public timely and accurate program-specific information on the performance of transplant programs. This shall include free dissemination over the Internet, and shall be presented, explained, and organized as necessary to understand, interpret, and use the information accurately and efficiently. These data shall be updated no less frequently than every six months (or such longer period as the Secretary determines would provide more useful information to patients, their families, and their physicians), and shall include risk-adjusted probabilities of receiving a transplant or dying while awaiting a transplant, risk-adjusted graft and patient survival following the transplant, and risk-adjusted overall survival following listing for such intervals as the Secretary shall

prescribe. These data shall include confidence intervals or other measures that provide information on the extent to which chance may influence transplant program-specific results. Such data shall also include such other cost or performance information as the Secretary may specify, including but not limited to transplant program-specific information on waiting time within medical status, organ wastage, and refusal of organ offers. These data shall also be presented no more than six months later than the period to which they apply;

(v) Respond to reasonable requests from the public for data needed for bona fide research or analysis purposes, to the extent that the OPTN's or Scientific Registry's resources permit, or as directed by the Secretary. The OPTN or the Scientific Registry may impose reasonable charges for the separable costs of responding to such requests. Patient-identified data may be made available to bona fide researchers upon a showing that the research design requires such data for matching or other purposes, and that appropriate confidentiality protections, including destruction of patient identifiers upon completion of matching, will be followed. All requests shall be processed expeditiously, with data normally made available within 30 days from the date of request;

(vi) Respond to reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes. The OPTN or Scientific Registry may impose charges for the separable costs of responding to such requests. An estimate of such charges shall be provided to the requester before processing the request. All requests should be processed expeditiously, with data normally made available within 30 days from the date of request; and

(vii) Provide data to an OPTN member, without charge, that has been assembled, stored, or transformed from data originally supplied by that member.

(2) An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary information regarding transplantation candidates, transplant recipients, donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate. Such information shall be in the form required and shall be submitted in accordance with the schedule prescribed. No restrictions on subsequent redisclosure may be imposed by any organ procurement organization or transplant hospital.

(c) Public access to data. The Secretary may release to the public information collected under this section when the Secretary determines that the public interest will be

served by such release. The information which may be released includes, but is not limited to, information on the comparative costs and patient outcomes at each transplant program affiliated with the OPTN, transplant program personnel, information regarding instances in which transplant programs refuse offers of organs to their patients, information regarding characteristics of individual transplant programs, information regarding waiting time at individual transplant programs, and such other data as the Secretary determines will provide information to patients, their families, and their physicians that will assist them in making decisions regarding transplantation.

§ 121.12 Advisory Committee on Organ Transplantation.

The Secretary will establish, consistent with the Federal Advisory Committee Act, the Advisory Committee on Organ Transplantation. The Secretary may seek the comments of the Advisory Committee on proposed OPTN policies and such other matters as the Secretary determines.